DAY FORM **Questions or assistances call: +45 9357 7750**

Day number: |__|__| **Date |__|__| - |__|__| - |__|__|__|__|**

#	Question	Answer	Unit	Info	Validation and limits	Further comments for data manager
Secondary outcome measures						
D1	Did the patient receive mechanical ventilation on this day?	☐ YES ☐ NO		Mechanical ventilation: invasive and non-invasive mechanical ventilation including continuous mask CPAP or CPAP via tracheostomy. Intermittent CPAP is NOT mechanical ventilation.	Required	
D2	Was the patient in coma at any time during this day?	☐ YES ☐ NO		Yes, if the patient had any of the following on this day (with or without any sedation): • RASS score from -3 to (-5) • Ramsey sedation score 4-6 • MASS score 1-0 • GCS ≤ 8 • RLS > 3	Required	
Delirium assessment						
D3	<u>Morning assessment</u> (during dayshift): Was the patient in coma at morning assessment?	☐ Yes ☐ No		YES, if the patient has any of the following at morning assessment (with or without any sedation): • RASS score from -3 to (-5) • Ramsey sedation score 4-6 • MASS score 1-0 • GCS ≤ 8 • RLS > 3	Required	Pre-filled with 'NO' if 'NO' in D2

D3a	Morning assessment (during dayshift): Did the patient have delirium at morning assessment?	☐ Yes ☐ No ☐ Not Assessed	YES, if the patient had any of the following at morning assessment: • CAM-ICU (positive) • ICDSC (≥ 4 points)	Required	Only if 'NO' in D3
D3b	Morning assessment (during dayshift): Was the patient described as hypo- or hyperactive at morning assessment?	☐ Hypo ☐ Hyper	Defined as: • **Hypo:** if the patient is considered HYPOactive and is positive for delirium at morning assessment (e.g. lying still with open eyes and no clear contact). • **Hyper:** if the patient is considered HYPERactive and is positive for delirium at morning assessment (e.g. agitated, non-corporative, pulling tubes and/or catheters).	Required	Only if 'NO' in D3 and 'YES' in D3a
D4	Evening assessment (during evening shift): Was the patient in coma at evening assessment?	☐ Yes ☐ No	YES, if the patient has any of the following at morning assessment (with or without any sedation): • RASS score from -3 to (-5) • Ramsey sedations score 4-6 • MASS score 1-0 • GCS ≤ 8 • RLS > 3	Required	Pre-filled with 'NO' if 'NO' in D2
D4a	Evening assessment (during evening shift): Did the patient have delirium at evening assessment?	☐ Yes ☐ No ☐ Not Assessed	Yes, if the patient has any of the following at evening assessment: • CAM-ICU (positive) • ICDSC (≥ 4 points)	Required	Only if 'NO' in D4 If 'NO' in both D3a and D4a a warning box appears **Note**: The patient meets pausing criteria. Please make sure to pause the trial medication and continue to screen

					the patient for delirium.
D4b	Evening assessment (during evening shift): Was the patient described as hypo- or hyperactive at morning assessment?	☐ Hypo ☐ Hyper	Defined as: • **Hypo:** if the patient is considered HYPOactive and is positive for delirium at evening assessment. Lying still with open eyes and no clear contact. • **Hyper:** if the patient is considered HYPERactive and is positive for delirium at evening assessment. (e.g. agitated and non-corporative, pulling tubes and catheters).	Required	Only if 'NO' in D4 and 'YES' in D4a
Delirium treatment					
D5	Was trial medication delivered to the patient today?	☐ YES ☐ NO ☐ Withdrawn	YES, if any dose was given during this day.	Required	Withdrawn only and automatically filled if patient is withdrawn
D5a	Why did the patient not receive trial medication?	☐ Patient meets pausing criteria ☐ Patient was in unexplained coma ☐ Other	Pausing criteria: If the patient had two consecutive (morning and evening assessment) negative CAM-ICU scores or ICDSC ≤ 4 **on the same day,** the patient meets pausing criteria and the trial medication should be paused. 'Patient was in unexplained coma' if the patient's coma is suspected due to trial medication and all other causes are considered unlikely (e.g. sedatives, analgesics) the clinician may pause trial medication. In doubt, please contact AID-ICU hotline: +45 9357 7750	Required	Only if NO in D5

			'Other' defined as any other reason not included by the above mentioned.		
D5b	Morning dose	☐ YES ☐ NO		Required	Only if 'YES' in D5
D5c	Midday dose	☐ YES ☐ NO		Required	Only if 'YES' in D5
D5d	Evening dose	☐ YES ☐ NO		Required	Only if 'YES' in D5
D5e	Did the patient receive additional as needed doses of trial medication during this day?	☐ YES ☐ NO		Required	Only if 'YES' in D5
D5f	How many additional as needed doses did the patient reveive?	|__|__|		Single-select	Only if 'YES' in D5e A maximum of 8 doses minus the given morning, midday and evening dose. If total exceeds 8 a warning appears: A maximum of 8 doses should be given. The coordinating team will be notified
D6	Did the patient receive escape medication during this day?	☐ YES ☐ NO		Required	
D6a	Which of the following escape medications were used?	☐ Propofol sedation ☐ α2 agonist ☐ Benzodiazepine		Multiple-select	Only if 'YES' in D6

D7	Did the patient receive any open-label **haloperidol (N05AD01)** during this day?	☐ YES ☐ NO		Required	If YES: Warning! PLEASE CONTINUE TRIAL MEDICATION AND DISCONTINUE OPEN-LABEL THERAPY
D8	Was the patient restrained at any time during this day?	☐ YES ☐ NO	Yes, if the patient has been physically restrained during this day. Physical restraint is defined as any mean of purposely limiting or obstructing the freedom of a person's bodily movement.	Required	
Serious Adverse Reactions If the patient experiences a SAR, the trial intervention must be stopped, and the coordinating center has to be contacted by e-mail aid-icu@cric.nu or phone +45 9357 7750 within 24 hours. Please complete withdrawal form, continue daily registration and complete follow-up.					
SAR1	Anaphylactic reaction on this day?	☐ YES ☐ NO	Urticaria **and** at least one of the following • Worsened circulation (> 20% decrease in blood pressure or > 20% increase in vasopressor dose) • Increased airway resistance (>20% increase in the peak pressure on the ventilation) • Clinical stridor or bronchospasm • Subsequent treatment with bronchodilators	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750

SAR2	Agranulocytosis on this day?	☐ YES ☐ NO	Any new, acute and severe drop in granulocytes to < 0.5 x 10^9/l requiring active monitoring or treatment	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750
SAR3	Pancytopenia on this day?	☐ YES ☐ NO	Any new, severe drop in red blood cells **AND** white blood cells **AND** platelets requiring active monitoring or treatment	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750
SAR4	Acute hepatic failure on this day?	☐ YES ☐ NO	Severe and progressing hepatic failure as judged by the treating doctor or the investigator.	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750
SAR5	Ventricular arrhythmia on this day?	☐ YES ☐ NO	Any first onset of ventricular arrhythmia (except PVCs) seen on ECG or continuous cardiac monitoring.	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750

SAR6	Extrapyramidal symptoms on this day?	☐ YES ☐ NO	Extrapyramidal symptoms include dystonia (continuous spasm and muscle contractions), akathisia (motor restlessness), parkinsonism (characteristic symptoms such as rigidity, bradykinesia and tremor). Mild forms of tremor or akathisia are NOT considered a SAR.	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750
SAR7	Tardive dyskinesia on this day?	☐ YES ☐ NO	Tardive dyskinesia is defined as rhythmical involuntary movements of tongue, face, mouth or jaw.	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750
SAR8	Malignant neuroleptic syndrome on this day?	☐ YES ☐ NO	Syndrome characterised by hyperpyrexia, muscle rigidity, catatonia, autonomic instability (irregular pulse or blood pressure, tachycardia, sweating, cardiac dysrhythmias)	Required	WARNING if YES Remember to discontinue the trial medication, complete the withdrawal form, and contact the coordinating centre within 24 hours at aid-icu@cric.nu or +45 9357 7750